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09/980,845	04/08/2002	Ann Progulske-Fox	00-505-B	3701

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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,845	PROGULSKE-FOX ET AL.	
	Examiner	Art Unit	
	AMBER D. STEELE	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *November 15, 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The amendment to the claims received on July 18, 2008 amended claims 2-3.

Claims 1-17 are currently pending and under consideration.

Priority

2. The instant application, Serial No. 09/980,845, filed 4/8/2002, states that it is the national stage of PCT/US00/21340, international filing date 8/4/2000; which claims benefit of U.S. Provisional Application 60/147,551, filed 8/6/1999.

Withdrawn Rejection

3. The rejection of claims 1-17 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 7,033,748 B2 is withdrawn in view of the terminal disclaimer received on April 10, 2009.

New Objections

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 6 is not described. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR

1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: since PCT/US00/21340 is part of a chain (i.e. chain of continuing data), reference to the PCT is required in the first line of the specification. While it is noted that an ADS is present in the application, the ADS states that the current application is a CON of the PCT. However, the present application is actually a National Stage (i.e. 371) of the PCT.

Appropriate correction is required.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

New Rejections

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 USC 112, first paragraph "Written Description" requirement, Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a **written description** rejection.

The various method claims are drawn to methods for identifying a polynucleotide which encodes a pathogen antigen comprising utilizing reagents including antibodies, antigens, pathogens, etc. The invention as claimed encompasses all known antibodies, antigens, pathogens, etc. and all potential antibodies, antigens, pathogens, etc. since virtually any antibodies, antigens, pathogens, etc. can be utilized in a screening assay. The claimed invention does not include any structural information regarding the antibodies or antigens.

The specification teaches a method of identifying polynucleotide sequences of SEQ ID NO: 1-8 (see Example 3) which encode antigens of *Actinobacillus actinomycetemcomitans* (please refer to pages 7 and 15-16 and Examples 1-3). In addition, the specification fails to teach a single example of the methods of claims 6 or 11-17. Therefore, one skilled in the relevant art would not reasonably conclude that the Applicants had possession of the invention as claimed.

See Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or

she was *in possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116.).

With the exception of SEQ ID NOs: 1-8 and *Actinobacillus actinomycetemcomitans* antigens as disclosed by the specification, the skilled artisan cannot envision the method of claims 1-5. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class wherein the specification provided only the bovine sequence.

The written description requirement for claims drawn to or utilizing antibodies and antigens require that either the antibody or antigen is taught due to the nature of antigen-antibody binding and the required specificity for useful products. For example, disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen. *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (holding there is a lack of written descriptive support for an antibody defined by its binding affinity to an antigen that itself was not adequately described). In addition, the limitations in claims 4, 10, and 17 regarding the animals and the limitations in claims 8-9 regarding the pathogens equate to a laundry list of potential animals and pathogens. A lack of

adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species).

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "microbe" in claim 8 is used by the claim to mean "a bacterium, a virus, a parasite, a prion, [or] a fungus" and claim 9 refers to more specific genera of bacterium and viruses, while the accepted meaning encompasses "a bacterium, a parasite, or a fungus" (i.e. small single or multicellular organism). The term is indefinite because the specification does not clearly redefine the term. Applicants may wish to modify the term "microbe" in all claims to "pathogen" (see present

specification page 10, line 10) which would encompass "a bacterium, a virus, a parasite, a prion, or a fungus".

11. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how antibodies can comprise sera (i.e. sera may comprise antibodies).

12. Claim 10 recites the limitation "the host" in line 1. There is insufficient antecedent basis for this limitation in the claim. Dependency on claim 7 is suggested.

13. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. The method of independent claim 1 has three method steps (i.e. a, b, and c). However, other potential method steps are present and it is not clear if these steps are required or not. After method step c, the statement "wherein a polynucleotide…is isolated and identified" is present. However, it is not clear if this is a separate method step (i.e. required method step for a proper nexus between the preamble and the method steps) or a "product-by-process" limitation regarding the reagent utilized in method step c (e.g. is "microbe's DNA or RNA" isolated and identified prior to making the expression library, etc.). In addition, method step a has statements that appear to be "product-by-process" limitations regarding the reagents utilized (i.e. antigens "that are expressed by the microbe *in vivo* and *in vitro*" and cell or cellular extracts of the

microbe "that have been grown *in vitro*"). Therefore, it is not clear if method steps regarding production of the antigens and cell or cellular extracts are required by the claims or not. If the method of independent claim 1 requires the antigens to be expressed *in vivo* and *in vitro*, cells or cellular extracts to be grown *in vitro*, polynucleotides expressed *in vivo*, and/or a polynucleotide to be isolated and identified, applicants are requested to provide positive method steps regarding these limitations into the claims. However, applicant is cautioned that no new matter may be added. Please also refer to present claims 2-3.

14. Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Method steps a and b have statements that appear to be a "product-by-process" limitations regarding the reagents utilized (i.e. cell or cellular extracts of the microbe "that have been grown *in vitro*"). Method steps d and e have statements that appear to be a "product-by-process" limitations regarding the reagents utilized (i.e. polynucleotides "are expressed *in vivo*"). Therefore, it is not clear if method steps regarding production of the cell or cellular extracts or polynucleotides are required by the claims or not. If the method of independent claim 11 requires the cells or cellular extracts to be grown *in vitro* or the polynucleotide to be expressed *in vivo*, applicants are requested to provide positive method steps regarding these limitations into the claims. However, applicant is cautioned that no new matter may be added.

15. Claims 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. Method steps a and b have statements that appear to be a "product-by-process" limitations regarding the reagents utilized (i.e. cell or cellular extracts of the microbe "that have been grown *in vitro*" and "route of infection" for how the microbe enters the host). Method steps d and e have statements that appear to be a "product-by-process" limitations regarding the reagents utilized (i.e. polynucleotides "are expressed *in vivo*"). Therefore, it is not clear if method steps regarding production of the cell or cellular extracts, polynucleotides, or route of infection are required by the claims or not. If the method of independent claim 13 requires the cells or cellular extracts to be grown *in vitro*, administration of microbes via the same or different route of infection, or the polynucleotide to be expressed *in vivo*, applicants are requested to provide positive method steps regarding these limitations into the claims. However, applicant is cautioned that no new matter may be added.

16. Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Method steps a and b have statements that appear to be a "product-by-process" limitations regarding the reagents utilized (i.e. cell or cellular extracts of the microbe "that have been grown *in vitro*"). Method steps d and e have statements that appear to be a "product-by-process" limitations regarding the reagents utilized (i.e. polynucleotides "are expressed *in vivo*"). Therefore, it is not clear if method steps regarding production of the cell or cellular extracts or polynucleotides are required by the claims or not. If the method of independent claim 15 requires the cells or cellular extracts to be grown *in vitro* or the polynucleotide to be expressed *in vivo*, applicants are requested to provide positive method steps regarding these limitations into the

claims. However, applicant is cautioned that no new matter may be added. After method step e, the statement "wherein if the polynucleotides expressed *in vivo* in the animal model and in the second host are the same or similar, then the animal model is confirmed as a valid model" is present. However, it is not clear if this is a separate method step (i.e. required method step for a proper nexus between the preamble and the method steps) or not. Applicants are requested to recite the confirmation as a positive method step.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-109 of copending Application No. 10/505,054 and claims 1-16 of copending Application No. 12/327,056. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions as claimed in U.S. applications 10/505,054 and

12/327,056 are drawn to methods of isolating a polynucleotide from a microbe utilizing antibodies and antigens.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. Please note: at this time the presently claimed methods are so indefinite that a meaningful search of the prior art could not be conducted. Applicants are requested to clarify the presently claimed methods so that a search of the prior art can be completed.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639

April 21, 2009